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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,486	08/11/2008	Marianna Cooley	079070.0117	1783

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EXAMINER

LEA, CHRISTOPHER RAYMOND

ART UNIT	PAPER NUMBER
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1619

NOTIFICATION DATE	DELIVERY MODE
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04/06/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/597,486	Applicant(s) COOLEY ET AL.	
	Examiner Christopher R. Lea	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-12 is/are allowed.
- 6) ☒ Claim(s) 1-9 and 13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/25/2006 & 4/5/2007</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This application is a 371 (national stage application) of PCT/US05/05190 which claims benefit from US Provisional application 60/542,636.

Claims 1-13 are pending. Claims 1-13 are under examination.

Information Disclosure Statement

1. The information disclosure statement(s) (IDS) submitted on October 25, 2006, and April 5, 2007, were filed before the mailing date of the first office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Any references not complying with 37 CFR 1.98 have been lined through and reason for non-compliance given on the form.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
4. Claims 1, 3-9, & 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. (US PreGrant Publication 2003/0170314) in view of Inoue (US Patent 3,926,646) as witnessed by Belfer et al. (US Patent 6,106,854), Dunivant ("White Line disease" 2000).

Applicant claims

Applicant claims an antimicrobial formulation comprising zinc oxide, a silver compound, a copper compound, and a bismuth compound. Applicant further adds other excipients to the formulation. Applicant also claims methods of using the formulation to treat various diseases and a kit containing the formulation.

Determination of the scope and content of the prior art (MPEP 2141.01)

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Burrell et al. teach, as a whole, compositions of metal containing compounds.

Claim 1, 3, 4, 9, & 13: Burrell et al. teach a composition containing metal containing materials which contain zinc, silver, copper and bismuth (paragraph 36). The silver containing materials may include silver nitrate (paragraph 36) and silver halides (paragraph 42). Copper oxides and zinc oxides are taught among the possible antimicrobial metal-containing materials (paragraph 42). Burrell et al. also teach including antimicrobial bismuth containing materials (paragraph 42). Bismuth subnitrate is an antimicrobial bismuth containing material (Belfer et al., column 3, lines 52-60).

Claim 5: Burrell et al. teach that the composition can be used to treat dental conditions (paragraph 53).

Claim 6: Burrell et al. teach that the composition can be used to treat skin irritation (paragraph 49)

Claim 7: Burrell et al. teach that the composition can be used to treat fungal infection (paragraph 49).

Claim 8: Burrell et al. teach that the composition can be used to treat bacterial and fungal infections of the nail and nail bed (paragraph 49). White Line disease in horses is a combination bacterial/fungal infection of the hoof (nail) bed (Dunivant, White Line Disease section).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

The difference between the teachings of Burrell et al. and the instant claims is that Burrell et al. do not exemplify all the claim limitations, i.e. the claimed ratios or the additional ingredients. This deficiency in Burrell et al. is cured by the teachings of Inoue.

Inoue teaches, as a whole, a method of setting a dental cement.

Claim 1: Inoue teaches that “phosphoric cements” are composed of primarily of zinc oxide with minor additional components such as copper, silver, and bismuth compounds (column 2, lines 19-65). Inoue teaches an example of a dental cement that contains 88% zinc oxide, with 2% of a bismuth compound (example I, column 4). While the reference is silent regarding some ratios, the difference in concentration will not support patentability unless there is evidence to indicating such concentration is critical. When the general conditions are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In the absence of evidence of critically, the claimed subject matter is considered obvious.

Claim 3: Inoue teaches a dental cement containing magnesium oxide (example I, column 4).

Claim 4: Inoue teaches adding phosphoric acid to the composition to form a dental cement paste (column 2, lines 19-28).

Claim 9: Inoue teaches the composition as part of a method to prevent tooth decay (column 2, lines 3-8).

Claim 13: Inoue teaches sodium fluoride among the fluoride sources which may be added to the principle cement powder prior to mixing with phosphoric acid to form a paste (column 2, lines 41-46). Hence the skilled artisan would have been motivated to

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package sodium fluoride with the metal compound-containing formulation; however, the skilled artisan would also have been motivated package the sodium fluoride separately due to its inhalation toxicity.

**Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)**

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the metal compound containing composition of Burrell et al. with the dental cements taught by Inoue and produce the instant invention. The skilled artisan would have been motivated to combine the teachings of Burrell et al. and Inoue because Inoue and Burrell et al. teach compositions known for the same purpose, namely treating dental diseases. It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art (See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) and MPEP § 2144.06).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in combining the metal compound containing composition of Burrell et al. with the dental cements taught by Inoue and producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention

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was made, as evidenced by the references, especially in the absence of evidence to the contrary.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burrell et al. and Inoue as applied to claim 1 above, and further in view of Kepner et al. (US Patent 6,383,273).

Applicant claims

Applicant claims an antimicrobial formulation comprising zinc oxide, a silver compound, a copper compound, ferric oxide, and a bismuth compound.

Determination of the scope and content of the prior art (MPEP 2141.01)

Detailed discussion of the rejection of claim 1 and the teachings of Burrell et al. and Inoue appears above.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the teachings of Burrell et al. and Inoue and the instant claims is that Burrell et al. and Inoue do not teach adding ferric oxide to the composition. This deficiency in Burrell et al. and Inoue is cured by the teachings of Kepner et al.

Kepner et al. teach, as a whole, compositions comprising a biocidal agent.

Kepner et al. teach inorganic iron compounds (such as ferric oxide) as among the possible biocidal agents in the composition (column 11, line 64 through column 12, line 48).

**Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)**

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to add ferric oxide as taught by Kepner et al. to the composition of Burrell et al. and Inoue and produce the instant invention. The skilled artisan would have been motivated to add ferric oxide because ferric oxide is an antimicrobial agent, hence it is known for the same function as the composition of Burrell et al. and Inoue. It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art (See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) and MPEP § 2144.06).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in adding ferric oxide to the composition of Burrell et al. and Inoue and producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Allowable Subject Matter

6. Claims 10-12 allowed.

7. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach or fairly suggest the specific formulations in the specific ratios comprised in claims 10-12.

Conclusion

Claims 1-9 & 13 are rejected. Claims 10-12 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571) 270-5870. The examiner can normally be reached on Mon-Thu 7:30-5:00 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRL

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616